Food Safety and Inspection Service Washington, D.C. 20250

Dr. Marc Cornelis Chief Veterinary Officer Federal Agency for the Safety of the Food Chain WTC III – (8th Floor) Simon Bolivarlaan 30 Brussels, B-1000 Belgium

MAY 0 2 2007

Dear Dr. Cornelis:

The Food Safety and Inspection Service (FSIS) conducted an on-site audit of Belgium's meat inspection system February 27 to March 5, 2007. Enclosed is a copy of the draft final audit report. You are invited to provide comments regarding the information in the audit report. Comments received from the government of Belgium will be included as an attachment to the final report. Comments must be provided within 60 days of the receipt of this letter.

If you have any questions regarding the FSIS audit or need additional information, please contact me at telephone number (402) 344-5100, by facsimile at (402) 344-5169, or electronic mail at donald.smart@fsis.usda.gov.

Sincerely,

Donald Smart

Director

International Audit Staff

Office of International Affairs

Enclosure

FINAL

JUL 25 2007

FINAL REPORT OF AN AUDIT CARRIED OUT IN BELGIUM COVERING BELGIUM'S MEAT INSPECTION SYSTEM

FEBRUARY 27 THROUGH MARCH 5, 2007

Food Safety and Inspection Service United States Department of Agriculture

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ABBREVIATIONS AND SPECIAL TERMS USED IN THE REPORT

CCA Central Competent Authority (Federal Agency for the Safety of the

Food Chain)

DG Directorate General

E. coli Escherichia coli

FASFC Federal Agency for the Safety of the Food Chain

FSIS Food Safety and Inspection Service

PCU Provincial Control Unit

PR/HACCP Pathogen Reduction/Hazard Analysis and Critical Control Point

Systems

Salmonella Salmonella species

SSOP Sanitation Standard Operating Procedures

U.S. United States

VEA European Commission/United States Veterinary Equivalence

Agreement

VIC Veterinarian-In-Charge

1. INTRODUCTION

The audit took place in Belgium from February 27 through March 5, 2007.

An opening meeting was held on February 27, 2007, in Brussels with the Central Competent Authority (CCA). At this meeting, the FSIS auditor confirmed the objective and scope of the audit, the FSIS auditor's itinerary and requested additional information needed to complete the audit of Belgium's meat inspection system.

The auditor was accompanied during the entire audit by a representative from the CCA, the Federal Agency for the Safety of the Food Chain (FASFC).

2. OBJECTIVE OF THE AUDIT

This was a routine annual audit. The objective was to evaluate the performance of the CCA with respect to controls over the processing establishment certified by the CCA as eligible to export meat products to the United States.

In pursuit of the objective, the following sites were visited: the headquarters of the CCA, and one meat processing establishment.

Competent Authority Visits			Comments	
Competent Authority	Central	1	Brussels	
Meat Processing Establishment		1	Hasselt	

3. PROTOCOL

This on-site audit was conducted in three parts. One part involved visits with CCA officials to discuss oversight programs and practices, including enforcement activities. The second part involved an audit of a selection of records in Belgium's inspection headquarters office. The third part involved an on-site visit to one meat processing establishment.

Program effectiveness determinations of Belgium's meat inspection system focused on five areas of risk: (1) sanitation controls, including the implementation and operation of Sanitation Standard Operating Procedures (SSOP) and Sanitation Performance Standards (SPS), (2) animal disease controls, (3) slaughter/processing controls, including the implementation and operation of Hazard Analysis/Critical Control Point (HACCP) systems, (4) residue controls, and (5) enforcement controls. Belgium's inspection system was assessed by evaluating these five risk areas.

During the on-site establishment visit, the FSIS auditor evaluated the nature, extent and degree to which findings impacted on food safety and public health. The FSIS auditor also assessed how inspection services are carried out by Belgium and determined if establishment and inspection system controls were in place to ensure the production of meat products that are safe, unadulterated and properly labeled.

At the opening meeting, the FSIS auditor explained to the CCA that its inspection system would be audited in accordance with three areas of focus. First, under provisions of the European Community/United States Veterinary Equivalence Agreement (VEA), the FSIS auditor would audit the meat inspection system against European Commission Directive 64/433/EEC of June 1964. This directive has been declared equivalent under the VEA.

Second, in areas not covered by this directive, the FSIS auditor would audit against Food Safety Inspection Service (FSIS) requirements. FSIS requirements include daily inspection in all certified establishments, the handling and disposal of inedible and condemned materials, species verification, and FSIS requirements for HACCP and SSOP programs.

Third, the FSIS auditor routinely audit against any equivalence determinations that have been made by FSIS. The following equivalence determinations have been made for Belgium:

- The use of ISO 11290-1 microbiology testing method for *Listeria monocytogenes* in ready-to-eat products.
- The use of ISO 6579:2002 microbiology testing method for *Salmonella* in ready-to-eat products and swine carcasses.

4. LEGAL BASIS FOR THE AUDIT

The audit was undertaken under the specific provisions of U.S. laws and regulations, in particular:

- The Federal Meat Inspection Act (21 U.S.C. 601 et seq.).
- The Federal Meat Inspection Regulations (9 CFR Parts 301 to end), which include the Pathogen Reduction/HACCP regulations.

In addition, compliance with the following Community Directive was also assessed:

• Council Directive 64/433/EEC of June 1964 entitled Health Problems Affecting Intra-Community Trade in Fresh Meat.

5. SUMMARY OF PREVIOUS AUDITS

Final audit reports are available on FSIS' website at the following address: http://www.fsis.usda.gov/Regulations_&_Policies/Foreign_Audit_Reports/index.asp

The two most recent FSIS audits of Belgium's meat inspection system were conducted in March/April 2005 and in December 2005.

March/April 2005 Audit

During the FSIS audit of Belgium's meat inspection system conducted in March/April 2005, the following deficiencies were identified:

- The methods being used to test for *Listeria monocytogenes* and *Salmonella* species were not FSIS methods and had not been submitted to FSIS for an equivalence determination.
- Testing of ready-to-eat products for *Salmonella* species was not being conducted at the required frequency of three times per year.

December 2005 Audit

During the FSIS audit of Belgium's meat inspection system conducted in December 2005, the following deficiencies were identified:

• In the one certified establishment audited, monitoring and verification records of the establishment did not include the time each entry was made.

During the current FSIS audit of Belgium's meat inspection system conducted February 27 through March 5, 2007, deficiencies identified during the December 2005 audit were found to be corrected.

6. MAIN FINDINGS

6.1 Legislation

The FSIS auditor was informed that the relevant EC Directive, determined equivalent under the VEA, had been transposed into Belgium's legislation.

6.2 Government Oversight

The FASFC has four Directors General (DG): one for Laboratories, one for Corporate Services, one for Control Policy, and one for Control. The DG for Laboratories is divided into internal (Government) and external (private) laboratories. Certain external laboratories are also public laboratories (e.g. universities). The DG for Corporate Services is responsible for human resource management, finance, and legal services. The DG for Control Policy (roughly equivalent to FSIS Office of Policy, Program, and Employee Development) establishes process standards. The DG for Control (roughly equivalent to FSIS Office of Field Operations) carries the responsibility for inspection/audit services and enforcement of process and product standards. This DG for Control is divided into eleven Provincial Control Units (PCU), one for each of the 10 Provinces and one for the capital city of Brussels. The DG for Control also has two Coordinators, one for the Flemish-speaking (northern) half of the country and one for the French-speaking (southern) half. These Coordinators supervise the Heads of the PCU

and ensure uniform distribution and implementation of the DG for Control Policy among the 11 PCU.

There are three Sectors under each PCU, each of which has a Sector Head. The three Sectors are:

- 1. Primary Production, responsible for live animals up to and including slaughter (areas of responsibility include animal welfare, animal disease, and controls of antibiotics and other veterinary pharmaceuticals) before sale in the markets.
- 2. Fabrication and Transformation (Processing), responsible for food (including meat processing), production of animal feed, and production of fertilizers and pesticides.
- 3. Distribution, responsible for markets and restaurants.

6.2.1 CCA Control Systems

When the management of an existing establishment wishes to become eligible to export to the U.S., the manager makes an application to the PCU. A Provincial Official Inspector conducts an administrative and technical inquiry and submits a report of the results to the Chief of the PCU, who, in turn, makes a recommendation to the DG Control Headquarters on the basis of the report. The final approval for U.S.-export certification is the responsibility of DG Control. To qualify for eligibility to export to the U.S., an establishment must first meet EC requirements and must be eligible to produce for intercommunity trade. If there is any question regarding the full eligibility of the establishment, a headquarters official from DG Control - Transformation may visit the premises on-site before a final approval is granted.

Communications regarding FSIS requirements are transmitted directly by the agricultural section of the U.S. Embassy in The Hague, Netherlands, to the Head of FASFC International Affairs (the Counselor General, DG Control Policy). This information is then transmitted, as well as other official guidelines and instructions that are issued by DG Control Policy, to the DG for Control. DG Control forwards them by e-mail and through the mail service to the Head of the PCU. The latter, in turn, provides them immediately to the Veterinarian-In-Charge (VIC).

To maintain U.S. certification, an establishment must be in compliance with a detailed audit of FSIS requirements. Officials from the PCU conduct the annual certification audit, periodic supervisory reviews, and ensure FSIS requirements continue to be met. If any of the requirements are not met, the PCU correlates with DG Control to determine if U.S. eligibility should be revoked.

6.2.2 Ultimate Control and Supervision

The VIC, of the establishment audited, is a full-time FASFC (Civil Service) employee, and provides inspection coverage of other establishments. There are also two contract FASFC (Assigned) veterinarians. They alternate inspection coverage with the VIC. They

have had similar inspection training, including official courses in HACCP and SSOP, as the VIC.

The National Implementation and Coordination Unit (NICU) provides oversight to ensure uniform distribution and implementation of DG Control Policy among the 11 PCUs by means of a comprehensive audit and inspection review program with established checklist, system controls, including reporting documents, system for analyzing data collected, and distribution of reports at all levels.

6.2.3 Assignment of Competent, Qualified Inspectors

Applicants wishing employment in the FASFC must pass a civil service examination. Specific additional examinations are prepared and required for veterinarians. The responsibility for the hiring of veterinarians and other inspection employees lies with the Minister of Public Health. The hiring process is conducted by Selor, a separate agency. The hiring of assigned/contract veterinarians is organized by the PCUs. Universities which offer a veterinary medicine curriculum, must offer public health courses and test accordingly. Both federally recruited and assigned/contract veterinarians must perform on-the-job training with an experienced official inspector. DG Corporate services maintain the Center for training and Development and offer targeted courses for official veterinary inspectors.

Both full-time and assigned/contract government employees are prohibited by law from performing any private, establishment-paid tasks at an establishment in which they perform official inspection duties. For full-time government employees, this is regulated in the law of February 4, 2000, "Creation of the Federal Agency for the Safety of the Food Chain." A private-practice veterinarian may be hired as a part time or contract government employee, but may not perform any private, establishment-paid tasks in any establishment in which he/she has official duties, nor may he have any additional conflicts of interest. This is regulated by the Royal Decree of December 19, 2002.

6.2.4 Authority and Responsibility to Enforce the Laws

Belgium law dated February 4, 2000; "Creation of the Federal Agency for the Safety of the Food Chain." grants the FASFC legal authority and responsibility to enforce Belgium meat inspection law. The Belgium Royal Decree dated May 16, 2001 describes the organizational structure of the FASFC. Third country specific export requirements, including U.S. requirements, are documented in the "Manual of Country Specific Export Requirements."

The VIC, as well as all other authorities in the chain of command up to DG Control, has full regulatory authority from retention of product up to and including suspension of operations.

6.2.5. Adequate Administrative and Technical Support

The Royal Decree dated April 15, 2005 constitutes the legal base to approve the external private laboratories but also the public laboratories. The five internal laboratories of the FASFC are also approved by this Royal Decree.

The Belgium Organization for Accreditation (BELAC) is the official accreditation body for accreditation of laboratories and is placed under the responsibility of the Federal Public Service for Economic Affairs.

Ongoing accreditation audits are conducted about every 18 months by a joint audit team comprised of representatives from BELAC and DC for Laboratories.

6.3 Headquarters Audit

The FSIS auditor conducted a review of inspection system documents. This records review was conducted at the headquarters office of FASFC in Brussels and at the FASFC inspection office located in the establishment audited. The records review focused primarily on food safety hazards and included the following:

- Internal review reports.
- Supervisory visits to the establishment that was certified to export to the U.S.
- Training records for inspectors.
- Label approval records.
- New laws and implementation documents such as regulations, notices, directives and guidelines.
- Laboratory accreditation and audit procedure.
- Sampling and laboratory analyses for microbiology.
- Sanitation, slaughter and processing inspection procedures and standards.
- Control of products from livestock with conditions such as tuberculosis, cysticercosis, etc., and of inedible and condemned materials.
- Export product inspection and control including export certificates.
- Enforcement records, including examples of intended legal action and criminal prosecution.

No concerns arose as a result of the examination of these documents.

7. ESTABLISHMENT AUDITS

The FSIS auditor audited the only meat processing establishment that was eligible to export meat products to the U.S. The establishment was not delisted and did not receive a Notice of Intent to Delist.

8. LABORATORY AUDITS

During laboratory audits, emphasis is placed on the application of procedures and standards that are equivalent to the U.S. requirements.

Residue laboratory audits focus on sample handling, sampling frequency, timely analysis data reporting, analytical methodologies, tissue matrices, equipment operation and printouts, detection levels, recovery frequency, percent recoveries, intra-laboratory check samples, and quality assurance programs, including standards books and corrective actions. No residue laboratories were audited.

Microbiology laboratory audits focus on analyst qualifications, sample receipt, timely analysis, analytical methodologies, analytical controls, recording and reporting of results, and check samples. If private laboratories are used to test U.S. samples, the FSIS auditor evaluates compliance with the criteria established for the use of private laboratories under the FSIS Pathogen Reduction/HACCP requirements. No microbiology laboratories were audited.

9. SANITATION CONTROLS

As stated earlier, the FSIS auditor focuses on five areas of risk to assess Belgium's meat inspection system. The first of these risk areas that the FSIS auditor reviewed was Sanitation Controls.

Based on the on-site audit of the establishment, Belgium's inspection system had controls in place for SSOP programs, all aspects of facility and equipment sanitation, the prevention of actual or potential instances of product cross-contamination, good personal hygiene and practices, and good product handling and storage practices.

In addition, Belgium's inspection system had controls in place for water records, chlorination procedures, back-siphonage prevention, separation of operations, temperature control, work space, ventilation, welfare facilities, and outside premises.

9.1 SSOP

The establishment was evaluated to determine if the basic FSIS regulatory requirements for SSOP were met, according to the criteria employed in the U.S. domestic inspection program. The SSOP program in the establishment was found to meet the basic FSIS regulatory requirements. No deficiencies were observed.

9.2 EC Directive 64/433

In the establishment, the provisions of EC Directive 64/433 were effectively implemented. No deficiencies were observed.

10. ANIMAL DISEASE CONTROLS

The second of the five risk areas that the FSIS auditor reviewed was Animal Disease Controls. These controls include ensuring adequate animal identification, control over condemned and restricted product, and procedures for sanitary handling of returned and reconditioned product.

No Belgian slaughter facilities were certified as eligible to export to the U.S. at this time. No deficiencies were observed during the review of records at the central office in Brussels or during the on-site audit of one processing establishment.

11. SLAUGHTER/PROCESSING CONTROLS

The third of the five risk areas that the FSIS auditor reviews is Slaughter/Processing Controls. The controls include the following areas: ante-mortem inspection procedures, ante-mortem disposition, humane handling and humane slaughter, post-mortem inspection procedures, post-mortem disposition, ingredients identification, control of restricted ingredients, formulations, processing schedules, equipment and records, and processing controls of cured, dried, and cooked products.

The controls also include the implementation of HACCP systems in all establishments and implementation of a generic *Escherichia coli (E. coli)* testing program in slaughter establishments.

11.1 Humane Handling and Slaughter

No Belgian slaughter facilities are certified as eligible to export to the U.S at this time.

11.2 HACCP Implementation

All establishments approved to export meat products to the U.S. are required to have developed and adequately implemented HACCP programs. These programs are evaluated according to the criteria employed in the U.S. domestic inspection program.

The HACCP program was reviewed during the on-site audit of the establishment. The establishment management had adequately implemented the HACCP requirements. No deficiencies were observed.

11.3 Testing for Generic Escherichia coli

No Belgian slaughter facilities were certified as eligible to export to the U.S. at this time. Therefore, the establishment was not required to meet the FSIS regulatory requirements for generic *E. coli* testing.

11.4 Testing for *Listeria monocytogenes*

The processing establishment audited had previously produced ready-to-eat products (pork shoulders and picnic hams) for export to the U.S. and currently this same establishment is not exporting any products to the U.S. This product was fully cooked in hermetically-sealed plastic pouches with no post-lethality exposure to the environment; therefore the establishment was not required to have a *Listeria* testing program as FSIS requires in 9 CFR 430.4. Even though the establishment is not currently producing ready-to-eat products, the CCA is required to conduct finished product testing on the same or similar product. Finished product testing is limited to "non-risk based testing" for

Listeria monocytogenes as mandated by FSIS Directive 10,210.1 Amendment 6, which requires product testing of three times per year. (Ready-to-eat products are required to be tested for both Listeria monocytogenes and Salmonella.) No deficiencies were observed.

11.5 EC Directive 64/433

In the establishment audited, the provisions of EC Directive 64/433 were effectively implemented. No deficiencies were observed.

12. RESIDUE CONTROLS

The fourth of the five risk areas that the FSIS auditor reviewed was Residue Controls. These controls include sample handling and frequency, timely analysis, data reporting, tissue matrices for analysis, equipment operation and printouts, minimum detection levels, recovery frequency, percent recoveries, and corrective actions.

No Belgian slaughter facilities were certified as eligible to export to the U.S. at this time. All meat products eligible for export to the U.S. are imported from eligible establishments in the Netherlands.

12.1 EC Directive 96/22

No Belgian slaughter facilities were certified as eligible to export to the U.S. at this time. Residue testing of incoming product is performed in the country of origin.

12.2 EC Directive 96/23

No Belgian slaughter facilities were certified as eligible to export to the U.S. at this time. Residue testing of incoming product is performed in the country of origin.

13. ENFORCEMENT CONTROLS

The fifth of the five risk areas that the FSIS auditor reviewed was Enforcement Controls. These controls include the enforcement of inspection requirements and the testing program for *Salmonella* species.

13.1 Daily Inspection in Establishments

Inspection was being conducted daily in the processing establishment audited on all days on which U.S.-eligible product was produced.

13.2 Testing for Salmonella in Raw Product

No Belgian slaughter facilities were certified as eligible to export to the U.S. at this time. Therefore, the establishment was not required to meet the FSIS regulatory requirements for *Salmonella* testing of raw product.

13.3 Species Verification

At the time of this audit, Belgium was required to test product for species verification. Species verification testing was being conducted as required.

13.4 Periodic Supervisory Reviews

During this audit, periodic supervisory reviews of the establishment audited were being performed and documented as required.

13.5 Inspection System Controls

The CCA had controls in place for restricted product, shipment security, including shipment between establishments, and prevention of commingling of product intended for export to the U.S. with product intended for the domestic market.

In addition, controls were in place for the importation of only eligible meat from other counties for further processing, security items, shipment security, and products entering the establishments from outside sources.

14. CLOSING MEETING

A closing meeting was held on March 5, 2007, in Brussels with the CCA. At this meeting, the primary findings and conclusions from the audit were presented by the FSIS auditor.

This Melhouthy

The CCA understood and accepted the findings.

Don Carlson, DVM

15. ATTACHMENTS

Individual Foreign Establishment Audit Form Foreign Country Response to the Draft Final Report

United States Department of Agriculture Food Safety and Inspection Service

Foreign Establishment Audit Checklist

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60. Observation of the Establishment

Date: 3/1/07 Est: B156[] (Hasselt Hasselt, Belgium)

There were no significant findings to report after consideration of the nature, degree and extent of all observations.



Federal Agency for the Safety of the Food Chain

DG Control Policy International affairs

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Your reference (Form 2630-9 (6/86)

Our reference PCCB/\$4/\$HS/ Enclosures

Date

Your letter from May 02, 2007

Form 2630-9 (6/86) PCCB/S4/SHS/
1 U. 07, 2007
FSIS on-site Audit of Belgium's meat Inspection system/ February 27 to

March 5, 2007/ comments report

Dear colleague,

Concerning the Food Safety and Inspection Service (FSIS) conducted on-site audit of Belgium's meat inspection system from February 27 to March 5, 2007, you will find below the comments of the Belgian authority regarding the information in the audit report:

1) Page 7, point 6.2 Government Oversight:

"The DG for Laboratories is divided into internal (Government) and external (private) laboratories."

The following sentence should be added: "Certain external laboratories are also public laboratories (e.g. universities)."

- 2) Page 9, point 6.2.5 Adequate Administrative and Technical Support:
 - "Royal Decree dated April 15, 2005 provides legal authority with guidelines to DG of laboratories to oversee...."

This should be adapted as follows:

"The Royal Decree dated April 15, 2005 constitute the legal base to approve the external private laboratories but also the public laboratories. The 5 internal laboratories of the FASFC are also approved by this Royal

Decree.

The Belgium Organization for Accreditation (BELAC) is the official accreditation body for accreditation of laboratories and is placed under the responsibility of the Federal Public Service for Economic Affairs.

"Ongoing accreditation audits are conducted every 16 months by a joint audit team..."

This should be adapted by "... are conducted about every 18 months..."

Our task is to preserve the safety of the food chain and the quality of food in order to protect the health of humans, animals and plants.

3) Page 13, point 13.3 Species Verification:

"At the time; of this audit, Belgium was not required to perform species verification testing."

It is unclear to us why species verification was not required at the time of the audit. Our inspection service meet with the species verification testing requirement for processed meat exported to the United States by continuing to conduct species verification testing via testing in the establishment (see also letter of May, 22, 2007 with reference PCCB/S4/SHS/165145).

If there are any questions, please feel free to contact the office of International affairs.

Yours sincerely,

Ir. H. DIRICKS

Director general

Cc: Dr. J.M. DOCHY: Director general, DG Control Ir. G. De Poorter, Director general, DG Laboratories